

APPLICANT(S): STEINER, Mitchell S. et al.
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REMARKS

Claims 1-32 are pending in the application. Claims 1-32 have been rejected. Claims 1, 2, 10, 11, 19, 21, 23-26, 28, and 30-32 have been amended. Support for amendments to claims 1, 2, 10, and 11 can be found throughout the specification as originally filed and particularly page 15, lines 4-5, page 24, line 9, etc. Amendments to the remainder of the claims are clerical in nature. Applicants assert that no new matter has been introduced.

Claims 4-6 and 13-15 have been canceled without prejudice or disclaimer. In making this cancellation without prejudice, Applicants reserve all rights in these claims to file divisional and/or continuation patent applications.

Applicants wish to thank the Examiner for the telephone interview conducted on May 20, 1997.

Double Patenting Rejections

In the Office Action, the Examiner alleged that there are several applications and issued patents subject to non-statutory obviousness type double patenting rejections. In an interview summary dated May 9, 2007, the Examiner provided a list of 47 patent applications and issued patents that she alleged are relevant to that rejection.

Applicants request that provisional obviousness-type double patenting rejections be held in abeyance until claims have been allowed in the referenced applications:

11/132,425 (US 2006/0287400)	10/609,684 (US 2004/0096510)
10/611,056 (US 2004/0092602)	10/305,363 (US 2003/0153625)
10/895,401 (US 2006/0019989)	11/656566
11/038,468 (US 2005/0171073)	11/604897
10/747,686 (US 2004/0186185)	11/329393
10/944,465 (US 2005/0080143)	11/324753
11/140,255 (US 2006/0270641)	11/220414
10/747,685 (US 2004/0176470)	11/184037

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11/140255	10/778333
11/132425	10/760152
11/013214	10/759538
11/003938	10/747691
10/995567	10/683161
10/963991	10/683160
10/944465	10/609684
10/895401	10/371155
10/861923	10/359270
10/861905	10/310150
10/778334	

United States Patent Number 6,413,534 (Attorney Docket Number: P-2769-US3) claims treating PIN with TOR, but does not specify a particular dose, whereas the subject application claims preventing and treating pre-malignant lesions of prostate cancer using a dose of 60 mg of the compound of formula (I). It would not have been obvious based on US 6,413,534 to use a dose of 60 mg. Applicants therefore request withdrawal of the rejection. Applicants will, however, provide a terminal disclaimer upon indication of allowable claims by the Examiner.

United States Patent Number 6,413,533 (Attorney Docket Number: P-2769-US2) claims treating latent prostate cancer or precancerous precursors with antiestrogens, whereas the subject application claims treating pre-malignant lesions of prostate cancer specifically with 60 mg of the compound of formula (I). It would not have been obvious based on US 6,413,533 to specifically use a dose of 60 mg of the compound of formula (I). Applicants therefore request withdrawal of the rejection.

United States Patent Number 5,413,535 (Attorney Docket Number: P-2769-US5) claims use of a metabolite or analog of TOR to treat or suppress premalignant lesions, whereas the subject application claims use of 60 mg of the compound of formula (I) to

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specifically treat pre-malignant lesions of prostate cancer. It would not have been obvious based on US 5,413,535 use any compound of formula I or its metabolite or analog to treat or suppress premalignant lesions. Applicants therefore request withdrawal of the rejection. Applicants will, however, provide a terminal disclaimer upon indication of allowable claims by the Examiner.

United States Patent Number 6,410,043 (Attorney Docket Number: P-2769-US4) claims treating prostate cancer or inhibiting latent prostate cancer with the compound of Formula I, whereas the subject application claims specifically treating or suppressing premalignant lesions with specifically 60 mg the compound of Formula I. It would not have been obvious based on US 6,410,043 to specifically use 60 mg the compound of Formula I to treat or suppress premalignant lesions. Applicants therefore request withdrawal of the rejection. Applicants will, however, provide a terminal disclaimer upon indication of allowable claims by the Examiner.

United States Patent Number 6,265,448 (Attorney Docket Number: P-2769-US) claims preventing prostate carcinogenesis with varying dosage ranges of the compound of formula (I), whereas the subject application claims specifically treating or suppressing premalignant lesions with specifically 60 mg the compound of Formula (I). It would not have been obvious based on US 6,265,448 to specifically use 60 mg the compound of Formula I to treat or suppress premalignant lesions. Applicants therefore request withdrawal of the rejection. Applicants will, however, provide a terminal disclaimer upon indication of allowable claims by the Examiner.

United States Patent Number 6,632,447 (Attorney Docket Number: P-2769-US6) claims SERM treatment of prostate cancer or inhibiting latent prostate cancer, whereas the subject application claims specifically treating or suppressing premalignant lesions with specifically 60 mg the compound of Formula (I). It would not have been obvious based on US 6,632,447 to specifically use 60 mg the compound of Formula I to specifically treat or

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suppress premalignant lesions. Applicants therefore request withdrawal of the rejection. Applicants will, however, provide a terminal disclaimer upon indication of allowable claims by the Examiner.

United States Patent Number 6,899,888 (Attorney Docket Number: P-4595-US) claims use of an anti-estrogen to treat androgen-deprivation induced osteoporosis, whereas the subject application claims treating or suppressing premalignant lesions of prostate cancer with 60 mg the compound of Formula (I). The claim scope of US 6,899,888 differs significantly from that claimed, as osteoporosis and premalignant lesions of prostate adenocarcinoma are distinct unrelated conditions. Applicants therefore request withdrawal of the rejection.

United States Patent Number 6,835,812 (Attorney Docket Number: P-2762-US2) claims a p-HYDE polypeptide sequence, which is completely unrelated to the compound of formula (I) and even less related to its use in treating pre-malignant lesions of prostate cancer specifically with 60 mg of the compound of formula (I). Applicants therefore request withdrawal of the rejection.

United States Patent Number 6,838,484 (Attorney Docket Number: P-5235-US4) claims a selective androgen receptor modulator (SARM), which is unrelated to the compound of formula (I) (a selective estrogen receptor modulator) and thus the scope of the '484 Patent and that claimed in the subject Application differ significantly. Applicants therefore request withdrawal of the rejection.

United States Patent Number 7,026,500 (Attorney Docket Number: P-5235-US10) claims a selective androgen receptor modulator (SARM), which is unrelated to the compound of formula (I) (a selective estrogen receptor modulator) and thus the scope of the '500 Patent and that claimed in the subject Application differ significantly. Applicants therefore request withdrawal of the rejection.

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CLAIM REJECTIONS

35 U.S.C. § 112 Rejections

In the Office Action, the Examiner rejected claims 1-32 under 35 U.S.C. § 112, first paragraph, though the Examiner's rejection is unclear as to whether an allegation of lack of enablement or written description/possession of the scope claimed is being set forth. Applicants disagree with either contention.

The Examiner alleged that no known drugs inhibit PIN/HGPIN, that the inhibition of PIN/HGPIN is an unpredictable art, and that it would require undue experimentation to determine predisposition to PIN and then determine when to administer the composition and at what dosage, thus the phrase "reducing the incidence" lacks enablement. Applicants disagree. It would be routine to a person of skill in the art to determine a reduction in incidence. Epidemiological studies are typically utilized to identify populations susceptible to PIN/HGPIN, and it is straightforward and well known in the art how to evaluate development of PIN/HGPIN in such populations, following administration of the claimed compound. Thus one skilled in the art would readily know how to prepare a 60 mg composition of toremifene, administer it to a population of subjects, and determine the reduction of incidence of PIN/HGPIN in treated subjects, in other words, how to make and use the invention. Applicants therefore request withdrawal of the rejection.

The Examiner alleged that the metabolites of claims 10 and 11 are not named in the specification and that not all metabolites are active. Applicants disagree. Metabolites of Toremifene are named on page 18, paragraph 57 of the Specification. Further, it is not necessary for every species to be functional in order that claims to a genus are considered enabled, and accordingly Applicants therefore request withdrawal of the rejection.

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In view of the foregoing amendments and remarks, the pending claims are deemed to be allowable. Their favorable reconsideration and allowance is respectfully requested.

Should the Examiner have any question or comment as to the form, content or entry of this Amendment, the Examiner is requested to contact the undersigned at the telephone number below. Similarly, if there are any further issues yet to be resolved to advance the prosecution of this application to issue, the Examiner is requested to telephone the undersigned counsel.

Please charge any fees associated with this paper to deposit account No. 50-3355.


Respectfully submitted,

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